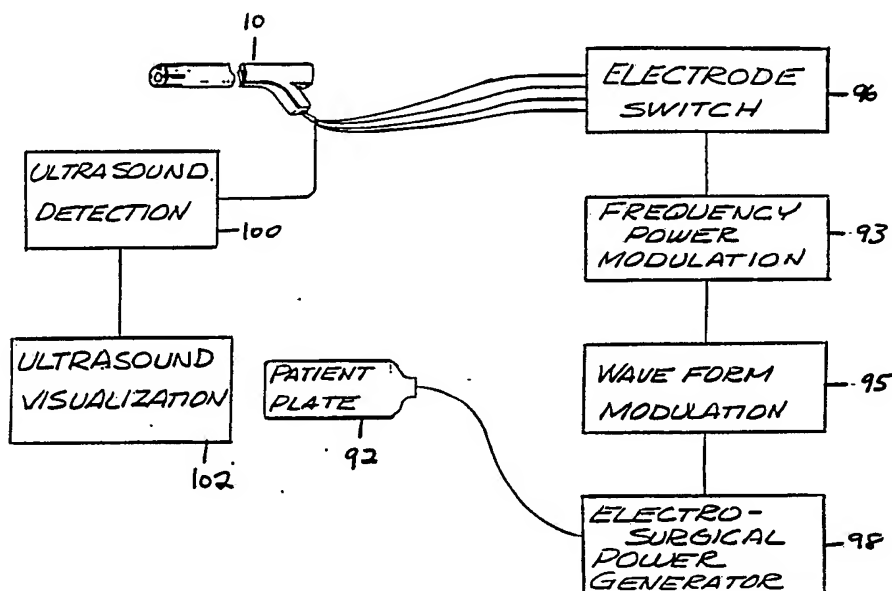




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

|  |           |  |
|--|-----------|--|
| <b>(51) International Patent Classification <sup>5</sup> :</b><br><br><b>A61B 17/39</b>  | <b>A1</b> | <b>(11) International Publication Number:</b> <b>WO 90/07303</b><br><br><b>(43) International Publication Date:</b> 12 July 1990 (12.07.90)  |
| <b>(21) International Application Number:</b> PCT/US90/00105<br><b>(22) International Filing Date:</b> 8 January 1990 (08.01.90)<br><b>(30) Priority data:</b><br>294,270                      6 January 1989 (06.01.89)                      US<br><b>(71) Applicant:</b> ANGIOPLASTY SYSTEMS, INC. [US/US];<br>Post Office Box 3368, Englewood, CO 80155 (US).<br><b>(72) Inventor:</b> JANSSEN, Michael ; 8179 S. Monaco Circle,<br>Englewood, CO 80155 (US).<br><b>(74) Agent:</b> SWANSON, Barry, J.; 4582 So. Ulster St. Pkwy.,<br>Suite 403, Denver, CO 80237 (US). |           | <b>(81) Designated States:</b> AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).<br><br><b>Published</b><br><i>With international search report.</i> |

**(54) Title:** ELECTROSURGICAL CATHETER FOR RESOLVING ATHEROSCLEROTIC PLAQUE

**(57) Abstract**

A method, and device utilized to practice it, for the resolution of tissue by radio frequency sparking. The device of the present invention having a distal end (20) which is insertable within and along the lumen of a tubular body member and manipulated therethrough to desired position where the device will be operated. The device comprises an elongated flexible hollow tube (12) having a distal end, a proximal end and a diameter smaller than the diameter of the tubular body member into which the device is being inserted; a passage (16) within the tube; a plurality of electrodes (14) adjacent the distal end of the device; and circuitry for selectively supplying radio frequency electrical current to at least one of said electrodes.

***FOR THE PURPOSES OF INFORMATION ONLY***

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

|    |                              |    |  |    |                          |
|----|------------------------------|----|--|----|--------------------------|
| AT | Austria                      | ES | Spain                                    | MG | Madagascar               |
| AU | Australia                    | FI | Finland                                  | ML | Mali                     |
| BB | Barbados                     | FR | France                                   | MR | Mauritania               |
| BE | Belgium                      | GA | Gabon                                    | MW | Malawi                   |
| BF | Burkina Faso                 | GB | United Kingdom                           | NL | Netherlands              |
| BG | Bulgaria                     | HU | Hungary                                  | NO | Norway                   |
| BJ | Benin                        | IT | Italy                                    | RO | Romania                  |
| BR | Brazil                       | JP | Japan                                    | SD | Sudan                    |
| CA | Canada                       | KP | Democratic People's Republic<br>of Korea | SE | Sweden                   |
| CF | Central African Republic     | KR | Republic of Korea                        | SN | Senegal                  |
| CG | Congo                        | LI | Liechtenstein                            | SU | Soviet Union             |
| CH | Switzerland                  | LK | Sri Lanka                                | TD | Chad                     |
| CM | Cameroon                     | LU | Luxembourg                               | TG | Togo                     |
| DE | Germany, Federal Republic of | MC | Monaco                                   | US | United States of America |
| DK | Denmark                      |    |  |    |                          |

5

"ELECTROSURGICAL CATHETER FOR RESOLVING ATHEROSCLEROTIC PLAQUE"

Field of Invention

10 The present invention relates to a device and method for resolving or removing atherosclerotic plaque build-up in an artery in order to improve blood flow. The device consists of an electrosurgical catheter which has a plurality of electrode sites, each capable of resolving plaque via radio frequency ("RF") sparking between the electrodes and the plaque. The current generated at the  
15 selected electrode is modulated so that the fatty material of the plaque is resolved without creating significant amounts of residue.

Background of the Invention

20 Various angioplasty techniques have been in use for several years. Typically, a catheter is introduced into the body through an artery in the leg or arm and threaded into the artery or blood vessel that has restricted blood flow due to the build-up of  
25 atherosclerotic plaque. The most common technique in current practice is balloon angioplasty. The catheter positioned within the subject artery has a deflated balloon at its tip. The balloon is inflated within the artery and the expansion of the balloon is designed to  
30 "press" the plaque into the artery wall, thereby minimizing blood flow restrictions. Balloon angioplasty generally just manipulates the form of the plaque, and does not create a significant problem of plaque residue flowing from the site. Unfortunately, balloon angioplasty  
35 has several failings and a relatively high complication rate.

Atherosclerotic plaque build-up can exist in a number of different forms. The plaque can be quite hard and scaly or more fatty and pliable. The areas of plaque  
40 accumulation are generally not symmetrically located at a

45

SUBSTITUTE SHEET

5 particular point in the artery, rather adhering to only portions of the artery walls.

Considerable efforts have been directed toward finding improved means to perform angioplasty procedures. Numerous devices recently have been described that utilize the application of heat to resolve atherosclerotic plaque. See for example, U.S. Patents Nos. 4,654,024 of Crittendon et al. and 4,748,979 and 4,672,962 of Hershenson. The most extensive research concerning the use of heat to resolve atherosclerotic plaque has been directed toward the area of laser angioplasty techniques. In most laser angioplasty devices the laser is used simply to supply heat to the tip of the catheter. See for example, U.S. Patents Nos. 4,784,133 of Mackin; 4,685,458 of Lechrone; 4,770,653 of Shturman; 4,662,368 and 4,773,413 of Hussein; and 4,732,448 and 4,641,912 of Goldenberg.

The various angioplasty techniques described in the literature uniformly fail to address the asymmetric disposition of the plaque within the artery. In most cases, the tip of the angioplasty catheter acts as if the plaque consists of a uniform symmetric coating on the interior wall of the artery. Particularly in those techniques which use something other than pressure to manipulate the plaque, the resolving forces are applied indiscriminately to the plaque and to the healthy tissue within the artery.

Radio frequency sparking to cut or cauterize tissue as a medical procedure is common in the prior art. There are two basic classes of electrosurgical devices. Monopolar devices consist of a high-frequency electrical (generally RF) generator, a cutting or cauterizing electrode or needle, and a patient plate. The patient plate is attached to the body of the patient, and acts as the return electrode for completion of the RF circuit. Cutting occurs due to the heat generated by RF sparking from the electrode to the patient's body tissue. The

5 shape of the electrode concentrates the RF energy, thus  
creating the high temperature spark. Appropriate  
modulation of the frequency determines whether cutting or  
cauterizing will occur. The relatively larger surface  
area of the patient plate, which is in contact with the  
10 patient's body, prevents the current flow from  
concentrating at one point. This prevents the RF current  
from burning the patient as the current exits the body.

There are also several bipolar electrosurgical  
devices described in the prior art. Bipolar devices  
15 consist of a high frequency electrical generator and an  
instrument that contains both the delivery and return  
electrode. RF sparking occurs between the two self-  
contained electrodes of the instrument. The bipolar  
electrosurgical devices of the prior art are generally  
20 inadequate due to the conditions necessary to create  
bipolar sparking. The most fundamental difficulty is that  
bioactive electrodes must have a roughly equal voltage  
drop at both the delivery and return electrodes. The high  
power current required in order to achieve bipolar arcing  
25 often causes extraneous sparking, particularly when there  
is unequal contact with the surrounding tissue.

The extension of known electrosurgical  
processes--utilizing RF sparking--to angioplasty  
techniques is relatively unexplored. A disclosure of a  
30 monopolar electrosurgical catheter for use in resolving  
atherosclerotic plaque is found in U.S. Patent No.  
4,682,596 of Bales. The mono and bipolar devices in Bales  
describe a hollow catheter with a hollow tip member. Only  
one potential electrode, at the catheter tip, is  
35 envisioned by the Bales patent. Bales briefly describes  
the utilization of variously modulated waveforms in order  
to resolve atherosclerotic plaque, and the application of  
high power levels while minimizing the creation of  
excessive amounts of heat. However, means are included  
40 for removing residue from the plaque destruction site,

5 indicating that the modulation techniques employed have not been maximized. It should be possible to destroy the plaque in such a manner so as to eliminate significant residue formation.

10 An article by Cornelius J. Slager et al. in the Journal of the American College of Cardiology entitled "Vaporization of Atherosclerotic Plaque by Spark Erosion" (June 1985, pp. 1382-6) describes the use of a bipolar RF sparking catheter. Again, there is a single spark generating electrode. The sparking frequency is  
15 modulated, but not to optimize ablation. Synchronous transmission of energy with cardiac contraction is employed in order to minimize the disruption of electrical pathways in the heart.

20 U.S. Patent No. 4,643,186 of Rosen describes an "antenna" type bipolar RF sparking catheter for use in angioplasty. The delivery and return electrodes are configured in such a way that the electrodes terminate together to form an "antenna."

25 When current is supplied to the antenna, RF sparking will occur. The addition of balloon means encapsulating the sparking antenna is also described. Rosen discloses coating the interior surface of such balloons in order to supply some control over the direction of sparking. Such directional manipulation can  
30 only be accomplished before the catheter is introduced into the patient's body. No means are disclosed for directing the random sparking of the "antenna" once introduced into the desired artery.

35 An example of an asymmetrically shaped electrode or energy applicator is seen in U.S. Patent No. 4,311,154 of Sterzer. The Sterzer patent discloses a device to be used in the treatment of a cancerous tumor with high temperatures, or hypothermia. Sterzer describes a device for hypothermic treatments utilizing microwave energy so  
40 that heat radiates nonsymmetrically from the surface of

5 the instrument. Sterzer does not utilize RF sparking and, like the Rosen patent, does not contemplate the use of means for directing the energy once the device is in place within the body.

10 The examples discussed above where RF sparking has been used for the resolution of atherosclerotic plaque employ relatively unsophisticated means. The RF spark is a very powerful and intense force to be let loose within the human body. Means for effectively harnessing the vast potential of RF sparking angioplasty have not been disclosed prior to this invention.

#### Summary of the Invention.

20 This invention relates to an improved device for the ablation or resolution of atherosclerotic plaque by use of RF sparking. The present invention adapts the electrosurgical electrode so that it may be incorporated into a catheter that may be manipulated to an arterial site of atherosclerotic plaque. The RF angioplasty catheter of the present invention has a segmented head, so that it is possible to control nonsymmetrical sparking from a plurality of electrodes.

25 Combined with real time visualization techniques, the device of the present invention allows for greater control and precision when utilizing RF sparking to resolve atherosclerotic plaque. The RF spark is an extremely powerful and concentrated source of heat within the artery. By the use of a segmented catheter head, the somewhat random nature of the sparking may be actively directed towards the section of the artery surface containing the plaque build-up of interest.

30 Controlling the direction of sparking from the electrode head makes it possible to increase the energy of the RF current utilized. By employing increased energy sparks, the material making up the atherosclerotic plaque may be almost totally disintegrated. The material

5 constituting the plaque may be reduced to such fine particles that removal of residue from the plaque resolution site is not necessary.

10 It is necessary to optimize the modulation of the RF current delivered to the sparking site. Even though the segmented catheter head greatly increases the specificity of the sparking action, it is still crucial to minimize temperature increases in the tissues surrounding the plaque. The higher energy sparks employed requires that pulsed modulation of the frequency be carefully controlled in order to allow the dissipation of heat to occur between the heat-generating spark pulses.

15 The catheter device of the present invention may have an elongated flexible hollow body that has a single open cavity capable of delivering fluids to the site of plaque resolution. At the far, or distal end, of the device, there is a plurality of sparking sites or electrodes spaced about the exterior circumference of the generally cylindrical catheter device. The RF energy transmitted to the distal end of the catheter may be selectively applied to any one of the various electrodes. Visualization of the artery will determine which wall or walls of the artery contain the plaque build-up to be resolved and will determine which electrode should be activated.

### 30 Brief Description of the Drawings

FIG. 1 is an isometric view of the distal end of an embodiment of the present invention.

35 FIG. 2 is a schematic view of a monopolar embodiment of the present invention.

FIG. 3 is a fragmentary axial cross-sectional view of the embodiment of the invention shown in FIG. 1.

FIG. 4 is a distal end view of the device shown in FIG. 3.



5           FIG. 5 is a radial sectional view of the device shown in FIG. 3 and is taken along the line 5-5 of FIG. 3.

          FIG. 6 is another radial sectional view of the device shown in FIG. 3 and is taken along the line 6-6 of FIG. 3.

10          FIG. 7 is an isometric view of the distal end of an embodiment of the present invention.

          FIG. 8 is a distal end view of an embodiment of the invention.

15          FIG. 9 is a radial sectional view analogous to FIG. 6 of an embodiment of the device.

          FIG. 10 is a radial sectional view analogous to FIG 5.

          FIG. 11 is a radial sectional view analogous to FIG 6.

20          Description of the Preferred Embodiment.

          FIG. 1 shows the distal end 20 of a atherosclerotic plaque resolving device constructed according to the teachings of the present invention.

25          FIG. 3 shows a cross-sectional view of the entire device, which is generally referred to, in total, as numeral 10. The device 10 is constructed, both by use of the appropriate size and materials, so that it may be inserted within and along the lumen of a blood vessel. Such

30          devices are generally referred to as catheters, and may be manipulated to the desired location in the blood vessel or artery. The desired location is the site of atherosclerotic plaque build-up. Usually, the plaque site is causing reduced blood flow through the vessel or

35          artery.

          The device and method of the present invention is particularly suited for the ablation of atherosclerotic plaque located within the arteries leading to the heart. The device and method disclosed herein has, however,

40          significant advantages over the prior art that may be

5        useful in a number of invasive surgical techniques. The  
device of the present invention may be used, for example,  
in the following procedures: the ablative treatment of  
fallopian tubes; the removal of colon obstructions, the  
removal of blood clots or tissue build-up within the blood  
10        vessels of the brain; and the removal of undesirable  
intestinal tissue. In each of these surgical  
procedures--and in the other invasive surgical  
techniques--a catheter is manipulated to the desired  
location within the body via the lumen of a tubular body  
15        member, and energy is applied to the distal end of the  
catheter in order to ablate or resolve tissue.

Introduction of the device 10 to the appropriate  
site may be accomplished by use of a guidewire. A  
guidewire, with the appropriate bends and turns, is  
20        "threaded" through an arterial pathway to the desired  
point of plaque build-up. The device 10 may then be  
easily passed over the path of the guidewire to the  
correct arterial site.

The device 10 includes an elongated hollow tubular  
25        body 12. The body 12 is usually flexible, and constructed  
of an electrically insulative material. Any of a number  
of polymeric or plastic materials may be employed for this  
purpose. The distal end 20 of the device 10 includes a  
plurality of electrodes 14. The electrodes 14 each  
30        constitute a monopolar electrosurgical electrode. The  
electrodes 14 may be constructed of any conductive metal  
or metallic alloy that is capable of retaining its form or  
shape when exposed to the extremely high temperatures  
generated by RF sparking. For example, the electrodes 14  
35        may be composed of stainless steel, tungsten, platinum,  
titanium, zirconium or any of the other so-called  
refractory metals. Alloys of the refractory metals may  
also be employed.

The distal end 20 of the device includes a  
40        generally flat end surface 22. The interior 16 of the

5 tubular body 12 of the catheter 10 has a generally  
constant diameter throughout the axial length of the  
catheter. Each of the electrodes 14 is separated from  
each other by the insulative material of the tubular body  
12, and exists in part on the circumference of the  
10 exterior surface of the tubular body 12 adjacent to the  
end surface 22, and in part planar to the end surface 22.  
Each electrode 14, therefore, consists of front 15 and  
radial 17 elements that are of unitary construction. The  
RF energy selectively delivered to each of the electrodes  
15 14 will create sparking from the electrode 14 to the  
atherosclerotic plaque.

In a monopolar device of the present invention as  
is schematically shown in FIG. 2, the return path for the  
RF current introduced into the body tissue is through a  
20 patient plate 92. The patient plate 92 is a relatively  
large dispersive plate that is attached to the body of the  
patient in order to establish contact with a significant  
amount of body surface area. The patient plate is  
typically placed onto the hip, thigh, buttock or belly of  
25 the patient. Conduction from the patient to the return  
electrode is maximized by applying electroconductive gel  
to the points of contact.

The device 10 may also be constructed as a  
"bipolar" RF sparking source. In such an embodiment, a  
30 single return electrode may be included among the  
plurality of electrodes 14 at the distal end of the device  
10. The RF sparking would thereby proceed from the  
selected electrode 14 to the return electrode. In such an  
embodiment a single return electrode may be a large  
35 conductive ring 93 distal to electrodes 14 with a surface  
area from 5 to 20 times larger than that of any of the  
delivery electrodes 14. In another bipolar embodiment of  
the present invention, the power generator output and  
return may be adapted so that any one of the plurality of  
40 electrodes can serve as either the delivery or return

5 electrode. For example, if the electrodes 14 in the  
device shown in FIG. 1 were numbered A-D and the plaque  
adjacent electrode A is twice that adjacent to  
electrodes B and C with the artery nearest electrode D  
containing no plaque, electrode A would be selected as the  
10 return electrode and B and C would be alternated as the  
delivery or anodic cathode. The plaque adjacent electrode  
A would receive twice the sparking energy as that adjacent  
electrodes B and C, and that adjacent electrode D would  
receive minimal amounts. In this embodiment, the  
15 directional specificity of sparking can be further  
controlled.

The device 10 is attached to and activated by a  
high-frequency, high voltage power supply 98. There are  
several such power generators marketed for use in  
20 electrosurgery. Typically, the energy is radio-frequency.  
Each electrode 14 is coupled to the power supply via a  
wire conductor 40 that runs the entire length of the  
tubular body 12. Each wire 40 may be electrically  
insulated.

25 The proximal end 50 of the catheter 10 has a "Y"  
shaped portion 52 that has a straight through passage 53  
and a branch passage 54. The interior 16 of the tubular  
body 12 may be accessed from either the straight through  
53 or the branch 54 passage. The wire conductors 40 are  
30 coupled to the generator, and prior to insertion into the  
catheter 10 via the branch passage 54 may be bundled  
together to form a single transmission wire 42, as shown  
in FIG. 9, or may remain separated.

The RF generator 98 must be adapted via an  
35 electrode switching device 96 such that the output of the  
generator may be selectively applied to one of the wire  
conductors 40, and therefore to one of the electrodes 14.  
Further modification of the generator via a device for  
waveform modulation 95 must be performed in order to  
40 create the optimized modulated waveform. The optimal

5 waveform provides a RF pulse of energy strong enough to  
create a spark that will disintegrate the atherosclerotic  
plaque with minimum residue formation. At the same time,  
the waveform must be modulated such that there is not an  
excess heat build-up in the tissue adjacent to the plaque  
10 destruction site. Appropriate time periods in which heat  
may be dissipated between bursts of energy will enable  
adequate cooling periods for the adjacent tissues.

It is thought that commonly available  
electrosurgery generator units may be adapted to provide  
15 the proper RF current; for example, a Bovie "Specialist"  
75 Watt ES, Electro-Surgery Unit or similar Valleylabs  
unit. The frequency of the wave form employed will be  
between 0.05 and 200 megahertz and the voltage will have a  
magnitude of several hundred volts. To achieve the  
20 optimum output modulation, a digital controller 93 will be  
connected in series with the generator to control pulse  
width of RF burst, on and off times and number of pulses.

The transmission wire 42 or wire conductors 40  
enter the catheter 10 via the branch passage 54 at the  
25 proximal end 50 of the catheter 10. In FIG. 9, the  
embodiment of the invention utilizing a single  
transmission wire 42, the transmission wire 42, which  
contains each of the wire conductors 40, is constructed so  
that each of the wire conductors 40 is electronically  
30 insulated from each other. In addition, the exterior  
surface of the transmission wire 42 is coated with an  
insulating material. In the preferred embodiment of the  
invention, each of the wire conductors 40 will be  
separately insulated, and will proceed separately through  
the catheter as seen in FIGs. 3, 5 and 6.

35 FIG. 6 shows a radial sectional view of the  
catheter 10 at a point between its distal 20 and proximal  
50 ends. As is shown, the wire conductors 40 are located  
within the interior cavity 16 of the tubular body 12. The  
40 wire conductors 40 are designed so that they will not take

5 up significant amounts of the interior 16 volume of the  
tubular body 12 and that the individual wires will not  
cross talk with each other. Room must be allowed for the  
passage of fluids to the plaque destruction site or to  
encompass the guide wire used to properly place the  
10 catheter 10.

As can be seen in FIG. 3, the wire conductors 40  
run nearly the full length of the tubular body 12. At  
some point 45 just adjacent the distal end 20 of the  
catheter 10, the individual wire conductors 40 proceed  
15 through the tubular body 12 and are coupled to the  
electrodes 14. FIG. 5 is a radial sectional view of the  
catheter 10 at the point 45 where the wire conductors 40  
each connect to its corresponding electrode 14.

FIGS. 10 and 11 show an additional embodiment of  
20 the invention wherein the wire conductors 40 are  
separately contained within separate lumens within the  
tubular body of the cathode 10.

The device 10 of the present invention is used  
for resolving or ablating atherosclerotic plaque or clots  
within the interior of vessels or arteries. The method of  
25 plaque resolution with such a device requires the use of  
some means for visualizing the interior of the vessel  
where plaque destruction is to occur. This can be  
accomplished by placing ultrasound transducers 85, as  
shown in FIG. 7 at the catheters distal end or under the  
30 electrodes 14. The transducers 85 send and receive  
ultrasonic signals which are processed using traditional  
ultrasonic processing means 100 and this displayed on  
video terminals 102 as shown in FIG. 2. Other  
35 visualization techniques would include, but would not be  
limited to, the following: the introduction of  
radionuclear dyes that allow for radiographic  
visualization use of other dyes suitable for introduction  
at the site of plaque destruction--or in the bloodstream  
40 generally--that are detectable by X-ray or other detection

5 techniques, high resolution biplane angiography, and fiber optics introduced along the catheter pathway that provide an actual picture of the interior of the artery or vessel.

10 Whatever means are used to determine the site of plaque build-up that requires treatment, the initial step is generally the placement of the catheter adjacent to the proposed destruction site. As described above, the appropriate positioning may be accomplished with the aid of a guidewire. Guidewires are constructed so that the wire will be introduced into an artery--either through the leg or arm--and threaded to the desired position. The  
15 placement of catheters is a well known and often performed procedure in connection with balloon angioplasty and other invasive surgical procedures. In the present invention the placement is critical not only with respect to the extension of the catheter distal end through an artery,  
20 but also with respect to the circumferential orientation of the catheter since the RF energy is applied differentially along the circumference to correspond to differential plaque build-up.

25 When utilizing a guidewire to help manipulate the distal end 20 of the catheter 10 to the appropriate location, the end of the guidewire exiting the patient may be used to guide the catheter 10 by use of the hollow interior 16 of the tubular body 12. The guide wire can be  
30 removed from the interior of the catheter when resolution is to begin, or may be maintained in place if required by the attending physician.

35 The interior cavity 16 of the catheter 10 may also be used to introduce fluids to the site of plaque destruction. For example, as an aid to visualization it may be desirable to flush the plaque destruction site. The introduction of dyes to aid the visualization process may also be accomplished via the interior cavity 16.

40 The interior cavity may also be valuable in order to place a fiber optic element at the site of

5 atherosclerotic plaque build-up. This could be accomplished by removal of the guidewire and introduction of the fiber optic--guided through the interior chamber--to the appropriate site.

10 The electrodes 14 at the tip of the distal end 20 of the tubular body 12 are shaped so that sparking may occur in both forward and radial directions. It is therefore possible to resolve plaque that has built up to such an extent that the catheter 10 is prevented from proceeding further along the arterial pathway. RF sparking from the front portions of the electrodes 14 will allow some forward directed sparking. Generally, the exterior diameter of the tubular body 12 is sized such that it is substantially smaller than the interior diameter of the arteries and vessels it will be encompassed by. Unless the atherosclerotic plaque build-up has progressed extremely far, it should be possible to place the distal end 20 of the catheter 10 in a position so that the plaque to be resolved will be generally planar to the side elements 17 of the electrode 14 selected to ablate the plaque.

25 Once the distal end 20 of the catheter 10 is properly placed, the operator must determine by consultation with the visualization technique utilized which surfaces of the artery or vessel require ablation. Rather than the random sparking delivered from the RF sparking electrodes of the current devices, it is possible to direct sparking towards those surfaces that require ablation.

30 In an additional embodiment of the device 10 (shown in FIGs. 7 and 8), the electrodes 14 consist of a plurality of split rings spaced along the exterior surface of the distal end 20 of the catheter. Each of the split rings 80 are separated from each other by a relatively small amount of the insulative material that comprises the bulk of the catheter 10. Each ring 80 is "split" into a



5 plurality of separate electrodes by equally spaced  
portions of insulative material. In such an embodiment it  
may be useful to incorporate end electrodes 89 on the  
relatively flat end of the distal end 20 of the catheter  
10 as seen in FIG 8. It would be possible to include a  
narrowed opening into the interior of the catheter to  
allow the expulsion of dyes or an interior catheter, as  
shown, or to "cap" the hollow catheter 10.

The embodiment of the invention shown in FIGs. 7  
and 8, as can the embodiment shown in Fig. 1, may be  
15 adapted to serve as either monopolar or bipolar  
electrosurgical catheters. The embodiment shown in FIG. 7  
has a total of 12 electrodes. When adapted to perform as  
a bipolar device in which each of the 12 electrodes may be  
selected to function as the anode or the cathode, the  
20 locational specificity for sparking at the site of plaque  
build-up is greatly enhanced. In such an embodiment, in  
addition to means for optimally modulating the wave form  
of the current flowing from the generator, the electrode  
switching means 96 must be adapted to select which of the  
25 electrodes will serve as the anode and which will serve as  
the cathode or return path.

30

35

40

45

CLAIMS

5

10

15

20

25

30

35

40

1. An electrosurgical tissue resolving device having a distal end which is insertable within and along the lumen of a tubular body member and manipulated there-through to a desired position where the device is operated to resolve tissue by radio frequency sparking, said device comprising:

(a) an elongated flexible hollow tube having a distal end, a proximal end, and a diameter smaller than the diameter of the tubular body member into which said device is being inserted;

(b) passage means within said tube;

(c) a plurality of electrodes adjacent to said distal end; and

(d) selection means for selectively supplying a radio frequency electrical current to at least one of said electrodes

2. The device of claim 1 wherein said radio frequency sparking occurs between said electrodes and said tissue and the current returns to said selection means via a patient plate attached to a remote portion of the subject.

3. The device of claim 2 wherein said tissue is atherosclerotic plaque.

4. The device of claim 2 wherein said tissue is a portion of the fallopian tube.

5. The device of claim 2 wherein said tissue is a blood clot or tissue build-up in the blood vessels of the brain.

6. The device of claim 2 wherein said tissue is intestinal blockage.

7. The device of claim 2 wherein said tissue is colon blockage.

8. The device of claim 2 wherein said electrodes consist of front elements and radial elements.

45

SUBSTITUTE SHEET

5           9. The device of claim 2 further comprising modulation means for modulating the wave form of said radio frequency electrical current so that said sparking will disintegrate said tissue while minimizing heat build-up in tissue adjacent to said tissue.

10           10. The device of claim 2 further comprising means for adjusting the electrical currents frequency, voltage and current so that said sparking will disintegrate said tissue while minimizing heat build-up in tissue adjacent to said tissue.

15           11. The device of claim 2 wherein said electrodes are composed of a refractory metal selected from the group consisting of stainless steel, tungsten, platinum, zirconium and titanium.

20           12. The device of claim 2 wherein said tube is an electrically insulative material.

          13. The device of claim 2 wherein said electrodes are electrically associated with said selection means via individual wires carried within said hollow interior of said tube.

25           14. The device of claim 2 wherein said proximal end has a "Y" shaped portion consisting of a straight through passage and a branch passage, and said straight through passage may be associated with means for supplying or removing fluids from the site of tissue resolution.

30           15. The device of claim 2 further comprising ultrasound transducers adjacent to said electrodes at said distal end.

35           16. The device of claim 2 wherein said electrodes consist of a plurality of split rings adjacent said distal end.

          17. The device of claim 16 further comprising electrically insulated end electrodes.

40           18. The device of claim 1 wherein one of said electrodes serves as a return electrode and said radio frequency sparking occurs between said electrodes and said return electrode.

5           19. The device of claim 18 further comprising means for selecting which of said electrodes will serve as said return electrode.

          20. The device of claim 18 wherein said tissue is atherosclerotic plaque.

10           21. The device of claim 18 wherein said tissue is a portion of the fallopian tube.

          22. The device of claim 18 wherein said tissue is a blood clot or tissue build-up in the blood vessels of the brain.

15           23. The device of claim 18 wherein said tissue is prostate blockage.

          24. The device of claim 18 wherein said tissue is colon blockage.

20           25. The device of claim 18 wherein said electrodes consist of front elements and radial elements.

          26. The device of claim 18 further comprising modulation means for modulating the wave form of said radio frequency electrical current so that said sparking will disintegrate said tissue while minimizing heat build-up in tissue adjacent to said tissue.

25           27. The device of claim 18 further comprising means for adjusting the electrical currents frequency, voltage and current so that said sparking will disintegrate said tissue while minimizing heat build-up in tissue adjacent said tissue.

30           28. The device of claim 18 wherein said electrodes are composed of a refractory metal selected from the group consisting of stainless steel, tungsten, platinum, zirconium and titanium.

35           29. The device of claim 18 wherein said tube is an electrically insulative material.

40           30. The device of claim 18 wherein said electrodes are electrically associated with said selection means via individual wires carried within said hollow interior of said tube.

5           31. The device of claim 18 wherein said proximal end has a "Y" shaped portion consisting of a straight through passage and a branch passage, and said straight through passage may be associated with means for supplying or removing fluids from the site of tissue resolution.

10           32. The device of claim 18 further comprising ultrasound transducers adjacent to said electrodes at said distal end.

15           33. The device of claim 18 wherein said electrodes consist of a plurality of split rings adjacent said distal end.

          34. The device of claim 33 further comprising electrically insulated end electrodes.

20           35. The device of claim 1 further comprising means for visualizing the interior surfaces of said desired position within said tubular body member.

          36. The device of claim 35 wherein said means employ ultrasound information.

          37. The device of claim 35 wherein said means employ fiber optics.

25           38. The device of claim 35 wherein said means employ radionuclear dyes.

          39. The device of claim 35 wherein said means employ high resolution biplane angiography.

30           40. A method of reducing the flow restriction effects of plaque or tissue located at a point in a tubular body member, comprising:

          (a) obtaining access to the interior of said tubular body member;

35           (b) inserting the distal end of catheter means consisting of an electrical conductors terminated in a plurality of electrodes into said tubular body member;

          (c) adjusting the position of said electrodes adjacent to said point;

40           (d) applying radio frequency energy to the distal end of said transmission line selectively so that

5        said energy will cause sparking from at least one of said electrodes.

10        41. The method described in claim 37 wherein said sparking occurs between said electrodes and said tissue and the current exits the subject via a patient plate.

15        42. The method described in claim 37 wherein one of said electrodes serves as a return electrode and said sparking occurs between said electrodes and said return electrode.

20

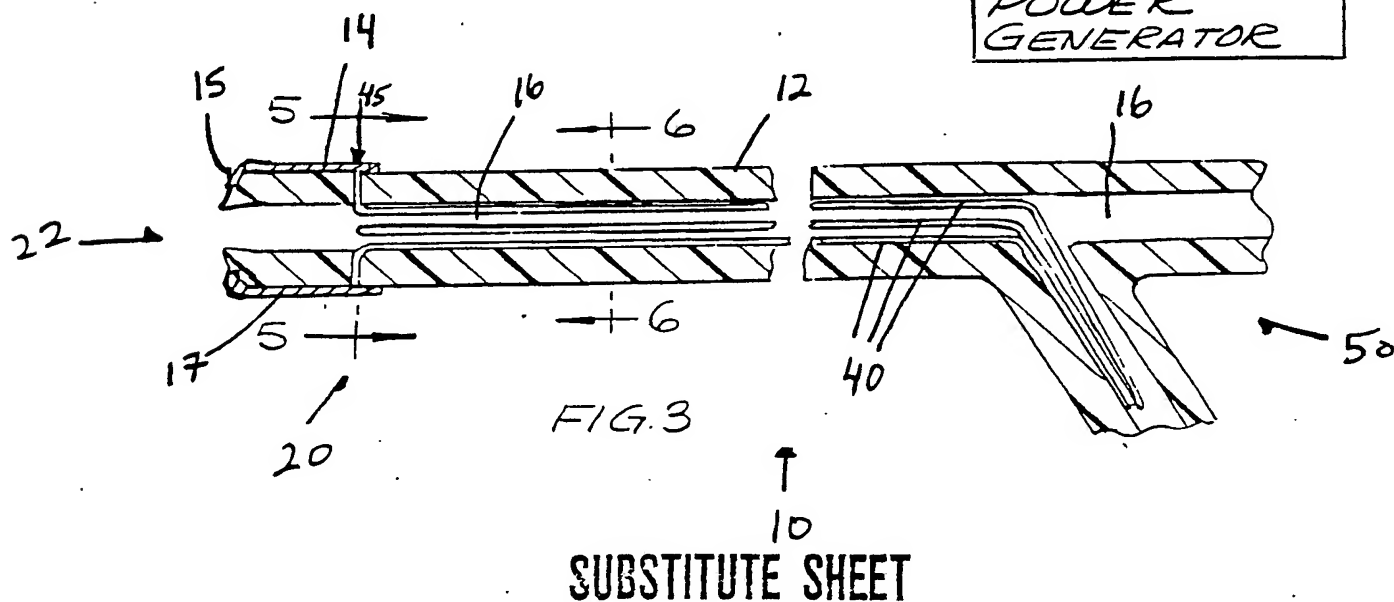
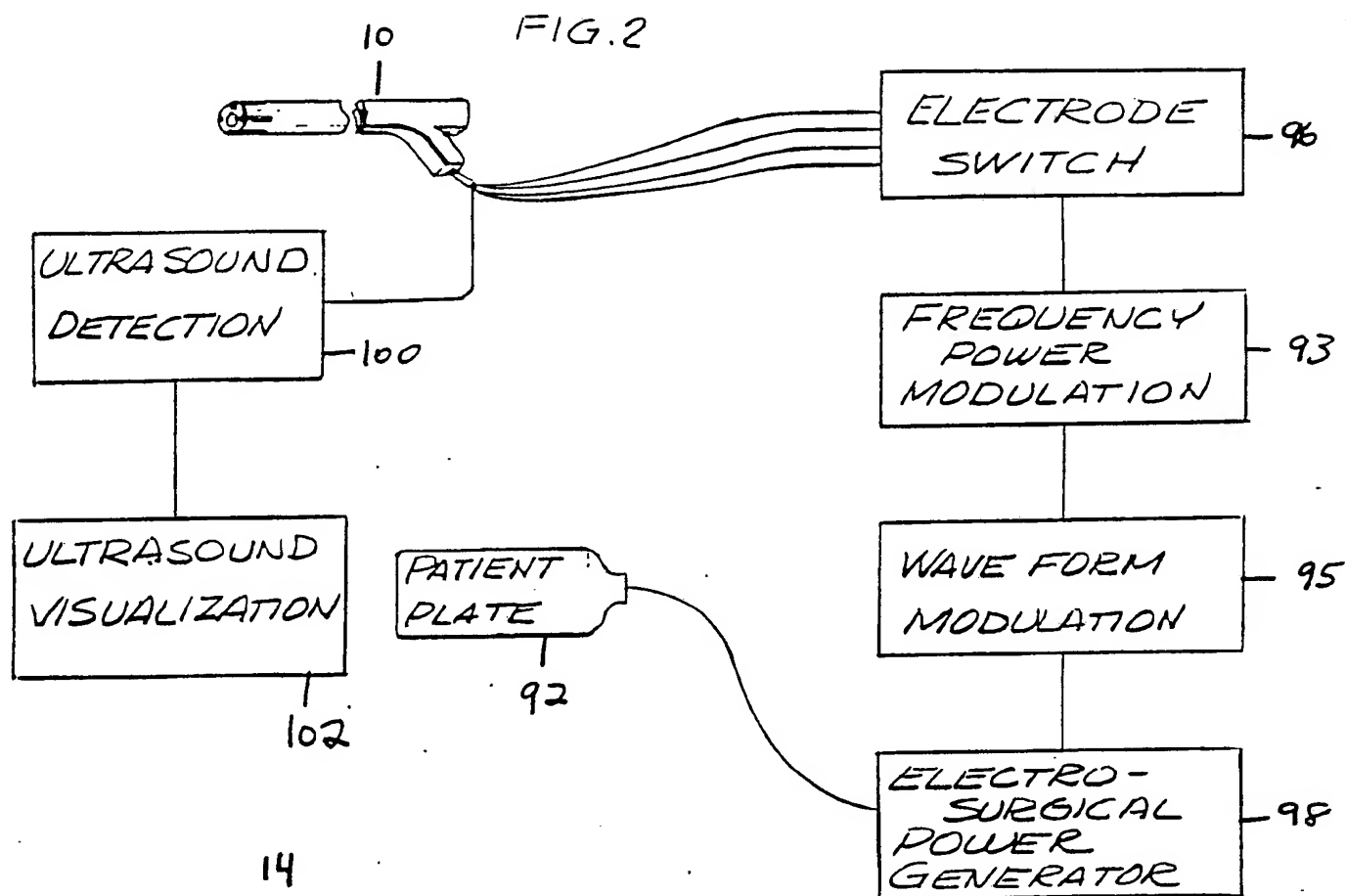
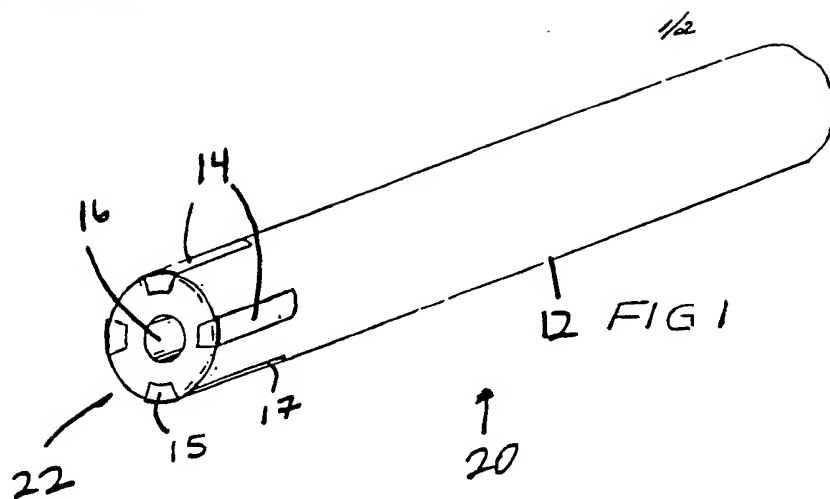
25

30

35

40

45



2/2

FIG 4

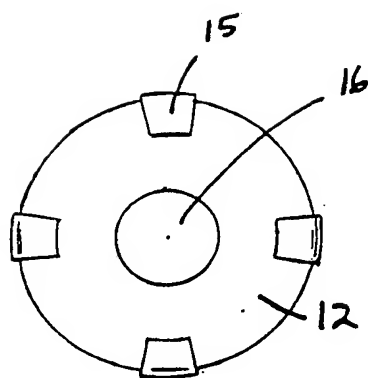


FIG 9

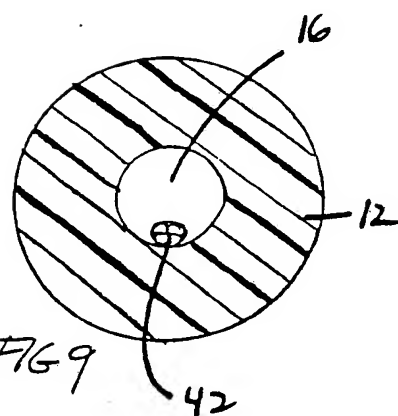


FIG. 5

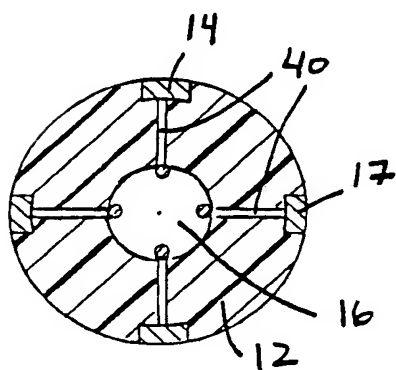


FIG 10

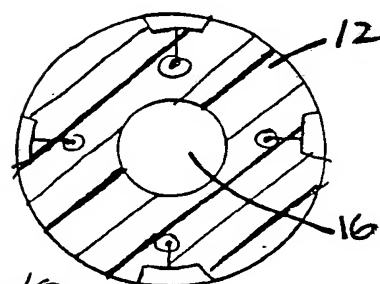


FIG. 6

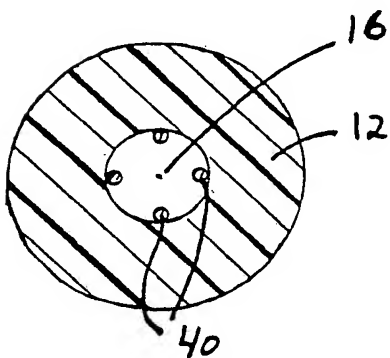


FIG. 11

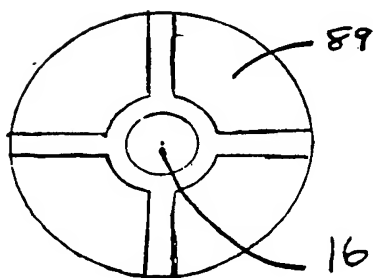
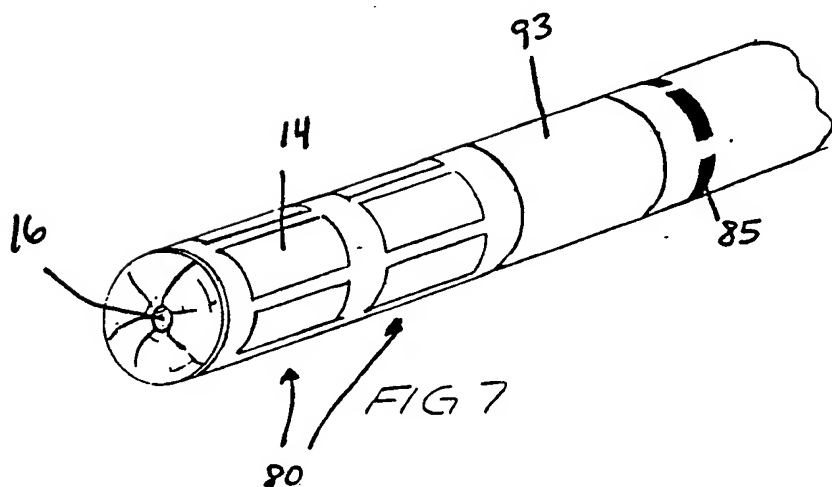
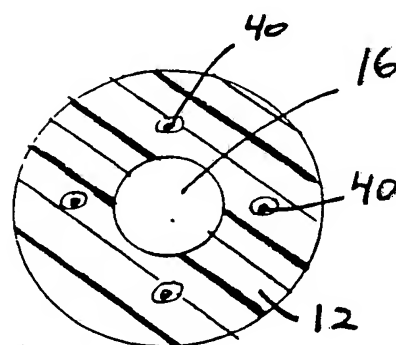


FIG 8



# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US90/00105

|  |   |   |
|--|---|---|
| <b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup>  |   |   |
| According to International Patent Classification (IPC) or to both National Classification and IPC<br>IPC(5) A 61 B 17/39<br>U.S. CL. 128/660.03; 606/48; 606/50 606/41   |   |   |
| <b>II. FIELDS SEARCHED</b>   |   |   |
| Minimum Documentation Searched <sup>7</sup>  |   |   |
| Classification System  | Classification Symbols  |   |
| U.S.   | 128/660.03, 786<br>606/33, 34, 41, 42, 45, 46, 48, 49, 50   |   |
| Documentation Searched other than Minimum Documentation<br>to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>  |   |   |
| <b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b>   |   |   |
| Category *   | Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>  | Relevant to Claim No. <sup>13</sup>   |
| X<br>Y   | US,A, 4,532,924 (AUTH), 06 AUGUST 1985. See entire document.  | 1, 18-25, 29, 30, 33, 34<br>8, 16, 17   |
| Y  | US,A, 4,576,177 (WEBSTER), 18 MARCH 1986. See entire document.  | 15, 32, 35-39   |
| A  | US,A, 4,643,186 (ROSEN), 17 FEBRUARY 1987. See entire document.   | 1   |
| X<br>Y   | US,A, 4,682,596 (BALES), 28 JULY 1987. See entire document.   | 1-7, 9-14, 18, 20-24, 26-31, 40-42<br>8, 16, 17   |
| A  | DE,A, 3,516,830 (HUEMANN), 13 NOVEMBER 1986. See entire document.   | 1   |
| A  | JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY, issued 1985, C. Slager, "Vaporization of Atherosclerotic Plaques by Spark Erosion", see pages 1382-1386. | 1   |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p><sup>10</sup> * Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p> </div> </div> |   |   |
| <b>IV. CERTIFICATION</b>   |   |   |
| Date of the Actual Completion of the International Search  |   | Date of Mailing of this International Search Report   |
| 07 February 1990<br>International Searching Authority  |   | <div style="font-size: 1.5em; font-weight: bold; margin-bottom: 10px;">13 MAR 1990</div> <div style="text-align: center;">             Signature of Authorized Officer<br/> <br/>             Lee S. Cohen           </div> |
| ISA/US   |   |   |